DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
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December 5, 2000

WARNING LETTER

NWE-03-01W

VIA FEDERAL EXPRESS

Richard H. Cohen, M.D., President
MedLean, Inc.
210 Bianca Road
Duxbury, Massachusetts 02332

Dear Dr. Cohen:

During an inspection of your Duxbury, Massachusetts facility, conducted on May 31, June 6 and 8, 2000, our Investigator determined that you are marketing and distributing AndrosteDERM, NOR AndrosteDERM and ProMALE.

This letter is in reference to your firm's marketing and distribution of these products. These products are labeled as dietary supplements. However, as these products are not ingested, they are not dietary supplements [section 201(ff) of the Federal Food, Drug, and Cosmetic Act (the Act)].

Labeling for these products contains claims which cause the products to be drugs [section 201(g) of the Act]. Labeling is not limited to the immediate product containers but includes all promotional literature which you distribute in connection with your products.

Objectionable claims for AndrosteDERM, NorAndrosteDERM, and ProMale include the following:

AndrosteDERM	"Transdermal testosterone precursor," "steady-state testosterone concentrations," "The benefits...preventing the natural decline of testosterone, increased muscle size and strength, improved muscle recovery, improved energy, enhanced libido, greater sense of well-being."
NorAndrosteDERM	"Transdermal nortestosterone precursor," "steady-state nortestosterone concentrations," "deliver natural anabolic hormone precursors," "The benefits...elevate levels of...nortestosterone... without elevating...testosterone and DHT...or causing an increase in estrogens, increased muscle size and strength, improved muscle recovery, improved energy, reduced joint pain, greater sense of well-being," "supports the formation of nortestosterone" which "provides ...increased muscle size, strength and recovery from training."
ProMALE	"Users of ProMale report the following benefits..."increased muscle size and strength, improved muscle recovery, improved energy, enhanced libido, greater sense of well-being," "When using ProMale...you can produce your own healthy levels of testosterone and nortestosterone," which "provides... increased recovery from training and injury," "improving energy, memory, immune function, and protection against age-related diseases," "reducing and lessening the effects of high levels of estrogen in the male body," "steady state support of testosterone production," "restore...testosterone."

Claims that these products can enhance libido or treat diminished sex drive or sexual ability cause them to be subject to 21 CFR 310.528, "Drug products containing active ingredients offered over-the-counter (OTC) for use as an aphrodisiac." The products listed above do not comply with this regulation.

The inclusion of the hormone ingredient, progesterone, in ProMale causes this product to be subject to 21 CFR section 310.530, "Topically Applied Hormone Containing Drug Products for Over-The-Counter Human Use." ProMale does not comply with this regulation.

In addition, these products are transdermal because they are intended to deliver active ingredients directly into circulation, to bypass the first pass effect on the liver, and are intended to have a systemic effect on the body. In 1989, the Agency made a determination that transdermal delivery systems are new drugs based on the newness of the delivery system [21 CFR section 310.3].

The formulation and labeling for AndrosteDERM, NOR AndrosteDERM and ProMALE do not meet the requirements of the regulations cited above. Therefore, they are new drugs according to Section 201(p) of the Federal Food, Drug and Cosmetic Act (the Act). A "new drug" may not be marketed in the United States without an approved new drug application (NDA) (Section 505(a) of the Act).

These drugs are also misbranded because their labeling fails to bear adequate directions for the conditions for which they are offered [section 502(f)(1) of the Act]. Further, these drugs are misbranded because their labeling is false and misleading [section 502(a) of the Act] since it suggests that these products are safe and effective for their intended use, when in fact, this has not been established through the new drug approval process.

This letter is not intended to be an all-inclusive review of all labeling and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We are aware that similar claims for these products are made on your firm's Internet Web site. In addition, this site includes a misleading statement that your transdermal products are manufactured in a FDA licensed facility. This implies that these products are in compliance with FDA regulations, when in fact, they are not. In addition, FDA does not "license" facilities. These Internet claims may also cause your products to be misbranded.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the Food and Drug Administration, New England District Office, One Montvale Avenue, Stoneham, Massachusetts 02180; Attention: Bruce R. Ota, Compliance Officer.

Sincerely,

Gail T. Costello
Director
New England District

cc: Nutrition Farm
305 Twin Branch Road
Campton, KY 41301

Enclosures:
21 CFR 310.3
21 CFR 310.528
21 CFR 310.530